

Attorney Docket No.: RTS-0343  
Inventors: Cowser and Freier  
Serial No.: 10/023,782  
Filing Date: December 17, 2001  
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#### REMARKS

Claims 1, 2, and 4-20 are pending in the instant application. Claims 15-20 have been withdrawn from consideration. Claims 1, 2 and 4-14 have been rejected. Claim 11 has been canceled. Claim 1 has been amended. No new matter has been added by these amendments to the claims. Reconsideration is requested in light of these amendments to the claims and the following remarks.

#### I. Restriction Requirement

The Restriction Requirement wherein claims 1-14 were placed into Group I and claims 15-20 were placed into Group II has been amended and then deemed proper and made Final. The amendment to the Restriction Requirement is that the Examiner was convinced by Applicants arguments that the claims identified in Group II are dependent claims upon claim 1 and are thus related. Accordingly, the Examiner has treated claim 1 as a linking claim which links Groups I through II and upon allowance of the linking claims, the restriction requirement shall be withdrawn and any linking claims depending from that claim shall be examined.

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## II. Rejection of Claim 1 Under 35 U.S.C. 112, Second Paragraph

Claim 1 has been rejected under 35 U.S.C. 112, second paragraph, because there is insufficient antecedent basis for the limitation of "said nucleic acid molecule encoding TFAP2C 1". Applicants have corrected the typographical error identified by the Examiner by removing the "1" from the name of the gene. Accordingly, withdrawal of this rejection is respectfully requested.

## III. Rejection of Claims Under 35 U.S.C. 102(e)

Claims 1, 2, 4, 5 and 11-14 have been rejected under 35 U.S.C. 102(e) as being anticipated by Dillon et al. (WO 01/40269 A2). The Examiner suggests that this patent discloses an antisense compound 10 to 40 nucleobases long that targets the TFAP2C polynucleotide, as well as generally disclosing that the antisense compounds contain internucleoside linkages and compositions in pharmaceutically acceptable carriers and diluents. Applicants respectfully traverse this rejection.

At the outset, claim 1, and by dependency claims 2, 4, 5 and 11-14, have been amended to recite that the antisense compounds of the instant invention are targeted to a specific nucleobase

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region within the sequence of SEQ ID NO: 3. Support for this amendment can be found throughout the specification as filed but in particular at pages 85-87.

Dillon et al. disclose the development of antisense compounds to breast cancer polynucleotides, including TFAP2C. Although the general idea of antisense is taught, nowhere does this patent teach or suggest antisense compounds as now claimed which are targeted to a specific nucleobase region of SEQ ID NO: 3. In order to anticipate an invention, the cited reference must teach each and every limitation of the claims (MPEP 2131). Accordingly, the reference fails to anticipate the claims as amended and withdrawal of this rejection is respectfully requested.

#### IV. Rejection of Claims Under 35 U.S.C. 102/103

Claims 1, 2, 11, 12 and 14 have been rejected under 35 U.S.C. 102(b) as anticipated by or under 35 U.S.C. 103(a) as being obvious over Cook et al. (US Patent 6,127,533). The Examiner suggests that this patent discloses a sequence which possesses 100% identity with nucleobases 2786 through 2804 of SEQ ID NO: 3 of the instant application and thus would inherently

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possess the function of the claimed compounds. Applicants respectfully traverse this rejection.

As discussed *supra*, Applicants have amended the claims to recite that the compounds are targeted to a specific nucleobase region of SEQ ID NO: 3, a region that does not include nucleobases 2786-2804.

Cook et al. disclose a single oligonucleotide compounds, SEQ ID NO: 22 that is reverse complementary to nucleobases 2786 through 2804 of SEQ ID NO: 3. No antisense compounds targeted to TFAP2C are taught or suggested by this reference, including any compounds as now claimed. In order to anticipate or make obvious an invention, the cited reference must teach each and every limitation of the claims (MPEP 2131 and 2143). This reference fails to teach the limitations of the claims as amended and cannot anticipate or make obvious the instant invention as now claimed. Withdrawal of this rejection is respectfully requested.

Claims 1, 2 and 11 have been rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Caskey et al. (US Patent 5,981,185). The Examiner suggests that this patent discloses a single sequence (SEQ ID NO: 10) that possesses 100% identity with nucleobases

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2166 through 2186 of SEQ ID NO: 3 of the instant application and thus would inherently possess the function of the claimed compounds. Applicants respectfully traverse this rejection.

As discussed *supra*, Applicants have amended the claims to recite that the compounds are targeted to a specific nucleobase region of SEQ ID NO: 3, a region that does not include nucleobases 2166-2186.

The patent discussed actually lists Matson et al. As the inventor, not Caskey. The patent discloses a single oligonucleotide compound, SEQ ID NO: 10 that is reverse complementary to nucleobases 2166 through 2186 of SEQ ID NO: 3. No antisense compounds targeted to TFAP2C are taught or suggested by this reference, including any compounds as now claimed. In order to anticipate or make obvious an invention, the cited reference must teach each and every limitation of the claims (MPEP 2131 and 2143). This reference fails to teach the limitations of the claims as amended and cannot anticipate or make obvious the instant invention as now claimed. Withdrawal of this rejection is respectfully requested.

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V. Rejection of Claims Under 35 U.S.C. 103(a)

Claims 1, 2 and 4-14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Dillon et al., Takahashi et al. (2000), McPherson et al. (1997), Taylor et al. (1999), Baracchini et al. (US Patent 5,801,154), and Bennett et al. (US Patent 5,998,148). The Examiner suggests it would have been *prima facie* obvious for one of ordinary skill to use the cDNA sequence of McPherson to generate antisense sequences as taught by Dillon et al. and Takahashi et al.. The Examiner claims it would have been obvious to modify such antisense using the modifications taught by Taylor et al., Baracchini et al., and Bennett et al. The Examiner suggests that motivation is provided by Dillon et al. and Takahashi et al. in teaching antisense to TFAP2C. The Examiner suggests that a reasonable expectation of success is provided by Taylor et al., Baracchini et al., and Bennett et al. Applicants respectfully traverse this rejection.

As discussed *supra*, the claims have been amended to recite that the compounds of the instant invention are directed to a specific nucleobase region of SEQ ID NO: 3.

Also as discussed *supra*, Dillon et al. teach the general concept of antisense but nowhere does this patent teach or

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suggest antisense compounds as now claimed which are targeted to a specific nucleobase region of SEQ ID NO: 3. Therefore, either alone or when combined, this reference does not make obvious the instant invention.

Takahashi et al. disclose a single antisense compound that targets TFAP2C. However, nowhere does this paper teach or suggest antisense compounds as now claimed which are targeted to a specific nucleobase region of SEQ ID NO: 3. Therefore, either alone or when combined, this reference does not make obvious the instant invention.

McPherson et al. disclose the cDNA sequence encoding TFAP2C of SEQ ID NO: 3. Nowhere does this paper teach or suggest antisense compounds of any kind targeted to any region of SEQ ID NO: 3.

Taylor et al. (1999) is a review paper on the technology of antisense. Although the paper suggests that screening only 3-6 oligomers per target is sufficient to find one that inhibits the gene with 66-95% efficiency, this paper does not provide any assurance that a specific gene, such as TFAP2C could be targeted successfully with antisense compounds as claimed.

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Baracchini et al. disclose antisense compounds to an entirely different gene. Although this patent provides teaching of the general technology of antisense, nowhere does this paper provide one of skill with teaching of antisense to TFAP2C of SEQ ID NO: 3.

Bennett et al. disclose antisense compounds to an entirely different gene. Although this patent provides teaching of the general technology of antisense, nowhere does this paper provide one of skill with teaching of antisense to TFAP2C of SEQ ID NO: 3.

To establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations. Clearly, the combination of prior art cited fails to establish a *prima facie* case of obviousness. There is no motivation provided in the references, as required, to combine references as claimed by the Examiner. Although two of the cited



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references teach the general art of antisense, the references cited that are specific to the gene claimed, have no mention or even suggestion of the development of antisense as claimed. It is only with the specification in hand that one of skill would understand how to target TFAP2C with antisense and how such compounds could be used successfully to inhibit expression of SEQ ID NO: 3. Thus, this combination of prior art fails to establish a *prima facie* case of obviousness and withdrawal of this rejection is respectfully requested.

#### VI. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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